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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,037	NALIN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-47* is/are pending in the application.

4a) Of the above claim(s) *43-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-42 and 47* is/are rejected.

7)☒ Claim(s) *34 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/24/05; 11/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note the change of examiner for this application. (Please see the Conclusion paragraph for information on any future correspondence.)

Claim Status

1. Claims 1-23 have been cancelled as filed on 1/24/05.

Claims 24-47 are currently pending.

Claims 43-46 have been withdrawn.

Claims 24-42 and 47 are being examined in this application.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 24-41 and 47) in the reply filed on 4/16/07 is acknowledged. The traversal is on the ground(s) that all the pending claims are linked by "a single general inventive concept" (Reply, entered 4/16/07, p.1). Applicants further cited the "International Search Report" for support of applicant's argument. This is not found persuasive because the International Search Report does not have a bearing on prosecution at the national stage. The International Search Reporter provides non-binding opinion of the PCT application (see MPEP 1845.01 section V; 1893.01). In addition, Applicants are respectively invited to see MPEP 1850 [R-3], PCT Rule 40.3, under the heading <THE REQUIREMENT FOR "UNITY OF INVENTION">, "Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT

Article 3(4)(iii) and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and **may be** relevant in the national (or regional) phase" (emphasis added). That is the holding of lack of unity at the national stage (the instant application) is not bound by what is previously done during the international stage. The requirement for restriction is bound by the propriety of the restriction practice under the PCT rule for unity of invention.

In addition, the ISR for the PCT application indicate that there are multiple inventions and the unity of invention is lacking (see Box II of ISR).

Applicants further state "The single general inventive concept is the modification of a target vector with a construct in order to be integrated into the genome of the host cell". (Reply, p.2, para 2). Without acquiescing to applicants' above assertion of the "general inventive concept", the instant pending claims do not even share this asserted "single general inventive concept". For example, the instant claim 45 is drawn to "a polynucleotide sequence", which does not recite any of the method or process features of "modification of a target vector with a construct in order to be integrated into the genome of the host cell". Thus, the different invention groups do not share a special technical feature according PCT Rule 13.1 and 13.2.

In addition, the common technical feature of Group I, molecular cloning steps of vector modification and cell transformation, or the technical feature asserted by applicants (i.e. "modification of a target vector with a construct in order to be integrated into the genome of the host cell") are known in the prior art. For examples, Rondon et al (Applied and Environmental Microbiology. Vol. 66(6): 2541-2547; 06/2000; cited in IDS), teach molecular cloning of DNA isolated from microbial samples using various cloning vectors (Abstract); Chain et al (Journal of

Bacteriology. Vol.182: 5486-5494; 10/2000), teach inserting oriT from RK2 into cloning vectors for site specific recombination of fragments of bacteria genomic DNA isolated from environment (e.g. Abstract; p.5484, Figures 1-2).

The requirement is still deemed proper and is therefore made FINAL.

3. Upon further consideration, the instant Claim 42 is rejoined with Group I invention. Thus, claim 42 is examined with Group I invention in the instant application.

4. Claims 43-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/16/07.

Priority

5. This application is filed under 35 U.S.C 371 of PCT/EP03/07765 (filed on 07/17/2003).

6. Receipt is acknowledged of papers (EP 022918718; 7/24/02) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

7. The IDS filed on 1/24/05 and 11/28/06 have been considered. See the attached PTO 1449 forms.

Drawings

8. The drawings/figures (see Figure 5) are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R.§§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Appropriate correction is required.

Specification

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. See MPEP 608.01.

Claim Objections

10. Claims 34 and 47 are objected to because of the following informalities:

A.) Claim 34 recites "the integrase is selected from ϕC31", which the "ϕC31" is a single entity and not a group of alternatives. It is suggested applicants amend claim 34 to remove the phrase "selected from".

B.) Claim 47 recites "the vectors are selected from cosmid, fosmid, P1 and BAC vectos" and is not written in a proper alternative format. It is suggested that applicants amend claim 47 to recite either "the vectors are selected from the group consisting of cosmid, fosmid, P1 and BAC vectors", or "the vectors are cosmid, fosmid, P1 or BAC vectors". See MPEP 2173.05(h).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposits

12. Claim 32 is rejected under 35 U.S.C 112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically "origin of transfer" (or nucleic acid molecules) "selected from RP4, pTiC58, F, RSF1010, ColE1, and R6K(α)". It is not clear that the entities represented by the said abbreviations are known plasmids or polynucleotides that are readily available to the public. Because the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. It is not apparent if the biological material or source materials are both known and readily available to the public. If the biological

materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a). during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

b.) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c.) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last requestor for the enforceable life of the patent, whichever is longer.

d.) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

e.) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to MPEP §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the

accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

Second paragraph of 35 U.S.C. 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 28-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 28 and 29 recite the limitation "the vector" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is not clear to which vector the term is referring. Claim 24 recites a "library of vectors", "selected cloning vectors" and modified cloning vectors.

B.) Claim 29 recites the limitation "the polynucleotide" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is not clear to which vector the term is referring. Claim 28 recites "a target polynucleotide construct", which appears to be different from "the polynucleotides" recited in Claim 24.

C.) Claims 30, 31, 33 and 35 recite the term "an origin of transfer functional", "functional", an integrase functional", and "a transcriptional promoter functional", respectively,

which the terms are indefinite. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). In this case, the claim language seems to recite the term "functional" as a noun describing an element in the cloning vector. However, the instant specification does not provide a clear definition for the term "functional". The closest term defined in the instant specification is "functional part" (spec. pp.15-17). The instant specification recites on page 15 (lines 27+), "The term 'functional part' designates any fragment or variants of the above sequence which retain the capacity to cause conjugative transfer" with the "above sequence" referring to SEQ ID NO:5. However, the instant specification also recites on page 17 (lines 25+), "The term 'functional part' designates any fragment or variants of the above sequence which retain the capacity to cause integration" with the "above sequence' referring to SEQ ID NO:6. The nucleic acid sequences of SEQ ID NO:5 and 6 are not the same and are structurally different with one referring to "oriT" and one referring to an integrase. It appears the term "functional part" is used to refer to completely different nucleic acid fragments. Thus, one of ordinary skill in the art would not be able to apprise the metes and bounds of the claimed invention.

D.) Claim 32 recites the terms "RP4, pTiC58, F, RSF1010, CoIE1, and R6K(α)", which terms are unclear and renders the claim indefinite. Neither the instant specification nor the claims define the said terms. It is not clear for what entity each of the abbreviations stands. Although the abbreviation "RP4" seems to indicate a "plasmid" (spec. p.15, line 9), it is not clear what specific

plasmid (with what nucleic acid sequence or structure) the plasmid comprise. Thus, one of ordinary skill in the art would not be able to apprise the metes and bounds of the claimed invention.

E.) Claims 37 and 38 recite "wherein the transposable nucleic acid comprises, flanked by two inverted repeats, the target polynucleotide..." which is not clear and renders the claim indefinite. It is not clear if all the recited elements "two inverted repeats, the target polynucleotide construct and a marker gene" are comprised by "the transposable nucleic acid", or if "the transposable nucleic acid" is "flanked by two inverted repeats, the target polynucleotide construct..." In addition, Claim 36 from which claim 37 depends on recite "the target polynucleotide construct comprises a transposable nucleic acid construct". However, Claim 37 seems to recite "the transposable nucleic acid comprises "...the target polynucleotide construct". Thus, one of ordinary skill in the art would not be able to determine with element(s) is/are comprised by the claimed "transposable nucleic acid".

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

Rondon

16. Claims 24-29, 35, 39, 41, 42 and 47 are rejected under **35 U.S.C. 102(b)** as being anticipated by Rondon et al (Applied and Environmental Microbiology. Vol. 66(6): 2541-2547; 06/2000; cited in IDS).

The instant claims recite a method of analyzing a library of polynucleotides, said polynucleotides being contained in cloning vectors having a particular host range, the method comprising (i) selecting cloning vectors in the library which contain a polynucleotide having a particular characteristic, (ii) modifying said selected cloning vectors to allow a transfer and integration of said vectors and/or of the polynucleotide which they contain into a selected host cell, and (iii) analyzing the polynucleotides contained in said modified vectors upon transfer of said modified vectors into said selected host cell.

Rondon et al, throughout the publication, teach molecular cloning of DNA isolated from microbial samples using various cloning vectors (Abstract).

The reference teaches construction BAC libraries made with DNA isolated directly from soil (e.g. p.2541, right col., para 2; p.2542, left col., para 1-2), which read on step (i) of **clm 42** as well as the unknown polynucleotides of **clms 25** and **26**, as well as the BAC vector of **clm 47**. The reference also teaches screening and analyzing the clones from the generated libraries (e.g. pp.2542-2543; especially bridging para) and selection of a certain construct such as the constructs that contain various genes (including cellulose, chitinase, keratinase, etc.) (e.g. p.2543), as well as "selecting" DNA with certain size from the generated libraries (e.g. p.2542, left col., para 3), which read on the "selecting step" of **clms 24** and **42**, as well as **clms 39** and **41**. The reference also teaches restriction digestion of the selected vectors, and then subsequent

ligation and transformation of the selected DNA (e.g. p.2542, cols, 1-2), which reads on the "modifying", "transferring" and "cloning" steps of **clms 24**, **28** and **42**. The reference's teaching also reads on the limitation of **clm 29**, because the insertion of the various DNA are inserted into the vector not into "the polynucleotide".

The reference teaches using various *E. coli* cloning vectors (e.g. pp.2541-2542), which reads on the vectors of **clm 27**.

The reference also inherently teaches the cloning vectors to have at least a promoter region as recited in **clm 35**, because the cloned DNA fragments are successfully expressed (e.g. pp.2542-2543) indicating a promoter region for transcriptional gene expression activation.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rondon and Chain

18. Claims 24-32, 35, 39-42 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rondon et al (Applied and Environmental Microbiology. Vol. 66(6): 2541-2547; 06/2000; cited in IDS), in view of Chain et al (Journal of Bacteriology. Vol.182: 5486-5494; 10/2000).

Rondon et al, throughout the publication, teach molecular cloning of DNA isolated from microbial samples using various cloning vectors, as discussed supra.

Rondon et al do not explicitly teach the target polynucleotide construct comprises an "origin of transfer functional" as recited in **clms 30-32**, as well as the inherent function of conjugative transfer as recited in **clm 40**. The abbreviation, RP4 recited in **clm 32** is construed as referring to the bacterial plasmid RP4.

However, Chain et al, throughout the publication, teach inserting oriT from RK2 (equivalent to RP4) into cloning vectors for site specific recombination of fragments of bacteria genomic DNA isolated from environment (such as soil) (e.g. Abstract; p.5484, Figures 1-2). The reference also inherently teaches "conjugative transfer" recited in **clm 40**, because "conjugative transfer" is an inherent property or a "natural DNA transfer mechanism" of constructs comprising "origin of transfer" (such as oriT from RP4) as evidenced by the instant specification (instant spec. p.14, lines 25+). In addition, the Chain reference also teaches the inherent property of conjugative transfer of the oriT element (Chain, p.5486, right col., para 2; p.5491, right col., para 1).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to insert "oriT" derived from RP4 or other plasmid into cloning vectors through the "natural DNA transfer mechanism".

A person of ordinary skill in the art would have been motivated at the time of the invention to insert oriT (or the origin of transfer) from RP4 plasmid in cloning or expression vectors, because utilization of these oriT DNA fragments offers the advantages of specific site

direct insertion of large fragments from bacteria genome to host E. coli genome as taught by Chain et al (e.g. Abstract).

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since both Rondon et al and Chain et al have demonstrated manipulation of various cloning vectors for insertion of desired DNA fragments such as oriT, nucleic acid fragment of interest, and host cell transformation as well as conjugative transfer are routine and known in the art.

Rondon, Chain, and Groth

19. Claims 24-35, 39-42 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rondon et al (Applied and Environmental Microbiology. Vol. 66(6): 2541-2547; 06/2000; cited in IDS), and Chain et al (Journal of Bacteriology. Vol.182: 5486-5494; 10/2000) as applied to claims 24-32, 35, 39-42 and 47 above, and further in view of Groth et al (PNAS. Vol.97: 5995-6100; 2000).

Rondon et al, throughout the publication, teach molecular cloning of DNA isolated from microbial samples using various cloning vectors, as discussed supra.

Chain et al, throughout the publication, teach inserting oriT from RK2 (equivalent to RP4) into cloning vectors for site specific recombination of fragments of bacteria genomic DNA, as discussed supra.

The combination of Rondon et al and Chain et al does not explicitly teach the target polynucleotide construct comprises an "integrase" as recited in **clms 33** and **34**. The term, "integrase functional" recited in **clm 33** is construed as referring to the enzyme "integrase" that is encoded by the target polynucleotide construct.

However, Groth et al, throughout the publication, teach inserting using phage C31 integrase to carry out recombination between DNA or interest and bacterial chromosome or human DNA (e.g. Abstract; pp.5995-5996).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include nucleic acids encoding for the phage C31 integrase in the cloning or expression vector for the purpose of integrating the desired DNA into the host cell genome.

A person of ordinary skill in the art would have been motivated at the time of the invention to include nucleic acids encoding for the phage C31 integrase in the cloning or expression vector for the purpose of integrating the desired DNA, because utilization of integrase offers the advantages of "precise unidirectional integration" with high efficiency as taught by Groth et al (e.g. Abstract).

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since Rondon et al, Chain et al and Groth et al have demonstrated manipulation of various cloning vectors for insertion of desired DNA fragments such as oriT, phage C31 integrase, nucleic acid fragment of interest, and host cell transformation as well as conjugative transfer are routine and known in the art and have shown to be successfully used for various molecular cloning processes.

Rondon, Chain, Groth, Berg and Devine

20. Claims 24-42 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rondon et al (Applied and Environmental Microbiology. Vol. 66(6): 2541-2547; 06/2000; cited

in IDS), Chain et al (Journal of Bacteriology. Vol.182: 5486-5494; 10/2000), and Groth et al (PNAS. Vol.97: 5995-6100; 2000) as applied to claims 24-35, 39-42 and 47 above, and further in view of Berg et al (PNAS. Vol.79: 2632-2635; 1982), and if necessary in view of Devine et al (US 5,728,551; 3/17/1998).

Rondon et al, throughout the publication, teach molecular cloning of DNA isolated from microbial samples using various cloning vectors, as discussed supra.

Chain et al, throughout the publication, teach inserting oriT from RK2 (equivalent to RP4) into cloning vectors for site specific recombination of fragments of bacteria genomic DNA, as discussed supra.

Groth et al, throughout the publication, teach inserting using phage C31 integrase to carry out recombination between DNA or interest and bacterial chromosome or human DNA, as discussed above.

The combination of Rondon et al, Chain et al and Groth et al does not explicitly teach the target polynucleotide construct comprises an "transposable nucleic acids", inverted repeats, and marker genes as well as using "transposase" for cloning vector modification as recited in **clms 36-38**.

However, Berg et al, throughout the publication, teach inserting using transposon elements for modifying DNA constructs (Abstract). The reference teaches the transposon DNA comprising inverted repeats, and marker gene such as Kan resistance gene (e.g. Figures 1-2). The reference also teaches using transposase for the DNA recombination process (e.g. p.2632, para 1; pp.2633-2634, bridging para). The reference also teaches inverse transposition where the Kan resistance gene is replaced by other drug resistance genes (e.g. Figure 2), which read on the

method steps of replacing the first marker gene with the second marker gene as recited in **clm 38**. The reference also teaches the advantages of using transposons such as their ability to recombine DNA without needing extensive DNA homology (e.g. p.2632, para 1).

Devine et al, throughout the patent, teach using transposons (with transposase) to facilitate DNA recombinant events (Abstract). The reference also teaches the advantages of "in vitro" transposon reactions such as high efficiency and versatility of the method (e.g. col. 5, lines 45+).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use transposon with transposase for desired DNA recombination such as insertion, deletion or mutation of DNA constructs in an in vitro or in vivo process.

A person of ordinary skill in the art would have been motivated at the time of the invention to use transposons with tranposase for either in vivo or in vitro recombining DNA to generate desired DNA constructs, because utilization of transposons/transposase especially in an in vitro process offers the advantages of DNA recombination without requiring DNA homology as taught by Berg et al, and high efficiency in an in vitro process as taught by Devine et al discussed above.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since Rondon et al, Chain et al, Groth et al, Berg et al and Devine have demonstrated manipulation of various cloning vectors for insertion of desired DNA fragments using various elements such as transposons are routine and known in the art and have shown to be successfully used for various molecular cloning processes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Patent Examiner, AU 1639
10/4/07

/Jon D. Epperson/
Primary Examiner, AU 1639